DEC 2 1 2011

CooperVision

510(k) Summary K112302

1. Applicant Name and Address	CooperVision, Inc. 6150 Stoneridge Mall Drive Suite 370 Pleasanton CA 94588	
2. Contact	Lisa Hahn Global Regulatory Affairs 585-385-6810 ext 4221 lhahn@coopervision.com	
3. Date Prepared	October 17, 2011	
4. Device Identification	Trade Name:	Proclear
	Common Name:	Scheduled Replacement Soft Contact Lenses for Daily wear or Daily Disposable Soft Contact Lenses
	Classification Name:	Daily Wear, Soft (hydrophilic) Contact Lenses
	Device Classification:	Class II (21 CFR 886.5925)
	FDA Material Class:	FDA Group II Non-Ionic High Water Content
	Product Code:	LPL and MVN

5. Device Description

The Proclear lens is composed of polymer of 2-hydroxy-ethylmethacrylate and 2-metacryloloyoxyethyl phosphorylcholine cross linked with ethylene glycol dimethacrylate. The lenses are tinted blue from edge to edge for visibility purposes. The Proclear *(omafilcon A)* Soft (hydrophilic) contact lenses are a hemispherical shell. The physical properties and available dimensions are unchanged from predicate 510ks.

Proclear Toric and Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are back surface toric.

Proclear Multifocal and Proclear Multifocal XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are available as a multifocal lens with an aspherical front surface and spherical back surface for the correction of

visual acuity in presbyopic persons who are myopic or hyperopic. The multifocal lens has two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength.

Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lens front surface is aspherical, with the anterior surface having a toric generated surface for the purpose of correcting vision in an eye that is astigmatic.

Proclear Sphere and Asphere: (*omafilcon A*) Soft (hydrophilic) Contact Lenses. The sphere lenses have spherical optical zone and asphere lens have an aspherical optical zone. This aspheric optical zone design (front surface) controls and limits the amount of longitudinal spherical aberration generated by the lens across the power range

6. Intended Use

Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with nondiseased eyes that are myopic or hyperopic which, possess astigmatism to -5.75 diopters or less, and are presbyopic.

Proclear Multifocal XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with nondiseased eyes that are myopic or hyperopic and are presbyopic. The lenses may be worn by persons who exhibit astigmatism of 0.75 diopters or less that does not interfere with visual acuity.

Proclear Toric XR (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic which possess astigmatism corrections to -5.75 diopters.

Proclear Sphere and Asphere: (*omafilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.

Proclear Toric: (*omafilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic or hyperopic The lens may be worn by persons who have astigmatism of 5.00D or less.

Proclear Multifocal: (*omafilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in non-aphakic persons with non-diseased eyes. The lens may be worn by persons who have astigmatism of 2.00D or less that does not interfere with visual acuity.

Proclear (*omafilcon A*) Soft (hydrophilic) Contact Lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

FREQUENT PLANNED REPLACEMENT WEAR
When prescribed for frequent planned replacement wear the lenses are to be cleaned, rinsed and disinfected each time they are removed from the patients' eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system

DISPOSABLE WEAR
When prescribed for Dally Disposable Wear the lens is to be discarded after each removal

7. Predicate Device(s)

Proclear Multifocal, Toric and Multifocal Toric (*Omafilcon A*) Soft Contact Lenses (K110099)

Proclear Sphere, Asphere, Toric, Multifocal and Multifocal Toric (*Omafilcon A*) Soft Contact Lenses (K061948)

8. Characteristics of Substantial Equivalence

The soft contact lenses have the following similarities to the predicate lenses which previously received 510(k) concurrence:

- have the same indicated use,
- incorporate the same design,
- incorporate the same materials,
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

The modifications to the hydration and inspection do not change the lens specifications or characteristics.

In summary, the omafilcon A soft contact lenses described in this submission are, substantially equivalent to the predicate device.

9. Physiochemical Studies

Results from physical, optical and chemical properties were performed and indicate no change to physicochemical properties of the lenses. Change does not affect physicochemical properties of the lenses.

Tested Characteristics Summary	Acceptance Criteria	Results
Total Extractables , Water content, Dk, Light Transmittance, refractive index tested per ISO 18369-4:2006 Ophthalmic optics – Contact lenses – Part 4: Physicochemical properties of contact lens materials: section 4.2	Equivalent to predicate lens and meet tolerances in ISO 18369-2:2006	Pass

Table 1: Material characteristics of the omafilcon A lens before and after modification.

Material Comparison		
Characteristic	**Subject Device**	**Predicate Device**
Product name	Proclear Toric Proclear Toric XR Proclear Multifocal Proclear Multifocal XR Proclear Multifocal Toric Proclear Sphere Proclear Asphere	Proclear Toric Proclear Toric XR Proclear Multifocal Proclear Multifocal XR Proclear Multifocal Toric Proclear Sphere Proclear Asphere
Material USAN Name	Omafilcon A	Omafilcon A
510(k) number	This submission	K110099 for material
FDA Category (Group)	Group II Non-Ionic High Water	Group II Non-Ionic High Water
Manufacturing method	Finished Inside Polymerization System II	Finished Inside Polymerization System II
Curing	Thermal Cure	Thermal Cure
Sterilization	Moist Heat (steam) in validated Autoclave	Moist Heat (steam) in validated Autoclave
Packaging	Blister Pack	Blister Pack
Visibility tint	VAT Blue 6	VAT Blue 6
Package Saline buffers and surfactant	Phosphate buffers PEG200 and Tween 80	Phosphate buffers Tween 80
Water Content	59% ± 2%	59% ± 2%
Refractive Index	1.395 ± 0.005	1.395 ± 0.005
Oxygen Permeability x 10^{-11}	21.05	21.05
Light Transmission	>90%	>90%
Base Curve	8.0 to .9.3 mm	8.0 to .9.3 mm
Diameter	13.6 to 15.2 mm	13.6 to 15.2 mm
Power	-20.00 to +20.00	-20.00 to +20.00

Comparison Conclusion: all the material characteristics for the omafilcon A lens are equivalent between the predicate lens and the subject lens (subject lens is omafilcon A made using FIPSII process with modified wet process).

10. Toxicology Studies

Results from in-vivo and in-vitro studies were performed as support for this modification and indicate no issues of toxicity or biocompatibility with the modified lens. Change will not affect lenses ability to remain non-toxic and biocompatible with the ocular environment.

A series of in-vitro and in-vivo preclincal toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens. All tests were conducted in accordance with the GLP regulation (21 CFR Part 56) or according to valid scientific protocols.

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Test	Acceptance Criteria	Result
Cytotoxicity Test ISO 10993 – 5: 1999: Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity	All 3 monolayers exposed to the test article show no grade greater than grade 2 (reactivity mild)	Pass
ISO Ocular Irritation ISO 10993 – 10:2002: Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed Hypersensitivity	Test extract shows no significant irritation over the reagent control during the observation period.	Pass
Systemic Toxicity Study ISO 10993 – 11: 1996: Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.	During the observation period, none of the animals treated with the individual test extract exhibit a significantly greater reaction that the control animals.	Pass
ISO Contact Lens 22 Day Ocular Irritation Study ISO 9394 Ophthalmic Optics – Contact Lenses and Contact Lens Care Products - The determination of Biocompatibility by Ocular Study with Rabbit Eyes.	Scores from macroscopic and microscopic ocular examinations equivalent between test and control eyes.	Pass

11. **Conclusions of Non-Clinical Tests Performed:**

- **Physiochemical:**

  The physical, optical and chemical properties of this lens remain unchanged from the unmodified device, and are within established specifications for the lenses.

- **Toxicology:**

  Results from in-vivo and in-vitro studies conducted verify that the lenses remain non-toxic and are biocompatible with the ocular environment.

12. Clinical Studies

The technical characteristics, formulation, manufacturing, and sterilization processes of this lens are not changing and are equivalent to omafilcon A soft contact lenses currently marketed by CooperVision, therefore no clinical data is required.

Conclusion Drawn from Studies:

Validity of Scientific Data Contract laboratories under Good Manufacturing Practice regulations conducted toxicological and microbiology studies.
Chemistry, shelf-life and leachablility studies were conducted by

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CooperVision and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7

Substantial Equivalence Information presented in this Premarket Notification establishes that the CooperVision (omafilcon A) Proclear Toric XR, Proclear Multifocal and Proclear Multifocal XR contact lens is as safe and effective as the predicate devices when used in accordance with the labeled directions for use and for the requested indications.

Risk and Benefits The risks of the subject lens are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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CooperVision, Inc.
C/O Lisa Hahn
Global Regulatory Affairs
6150 Stoneridge Mall Road
Pleasanton, CA 94588

Re: K112302
Trade/Device Name: Proclear (omafilcon A) Soft Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL and MVN
Dated: November 17, 2011
Received: November 18, 2011

Dear Ms. Hahn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

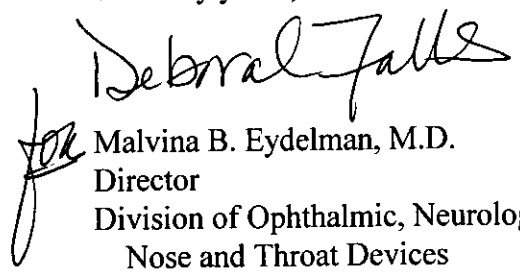
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112302

Device Name: Proclear (omafilcon A) Soft (hydrophilic) Contact Lenses

Indications for Use:

Proclear Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with nondiseased eyes that are myopic or hyperopic which, possess astigmatism to -5.75 diopters or less, and are presbyopic.

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Proclear Sphere and Asphere: (*omafilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.

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FREQUENT PLANNED REPLACEMENT WEAR
When prescribed for frequent planned replacement wear the lenses are to be cleaned, rinsed and disinfected each time they are removed from the patients' eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system

DISPOSABLE WEAR
When prescribed for Dally Disposable Wear the lens is to be discarded after each removal

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

J. Angelo Green

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112302